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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| 10/532,873 | 04/28/2005 | Tetsuya Ishii | Q72768 | 2291 |
| 23373 | 7590 | 12/11/2006 | EXAMINER | |
| SUGHRUE MION, PLLC | | | REDDY, KARUNA P | |
| 2100 PENNSYLVANIA AVENUE, N.W. | | | | |
| SUITE 800 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20037 | | | 1713 | |

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/532,873 | ISHII, TETSUYA |
| | Examiner | Art Unit |
| | Karuna P. Reddy | 1713 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/28/2005, 12/21/2005.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application
- 6) Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claim 1, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroya et al (JP 62-111918).

Kuroya et al disclose an application agent containing 3 to 30 wt% of monovalent salt of polyacrylic acid, 0.005 to 0.2 wt% of Al salt as a cross-linking agent, moisture content in the amount of 20-80 weight % and polyhydric alcohol. The application agent further comprises a carboxyl containing hydrophilic polymer such as carboxyvinyl polymer (abstract).

3. Claims 1, 3- 5, 7- 8, 10-11, 16, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Donati et al (EP 1046395).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The composition further contains a pharmaceutically acceptable diclofenac salt (page 4, line 1). The hydrogel mixture preferably comprises a wetting agent chosen

from polyhydric alcohols such as glycerol, propylene glycol, sorbitol etc (page 3, paragraph 0018) in a concentration of 5 to 70 wt% (page 3, paragraph 0019).

The hydrogel mixture further contains a polymer compound such as polyvinyl pyrrolidine having high affinity for polyhydric alcohol in the amount of 2.0% and a pharmaceutically acceptable diclofenac salt (page 4, line 1, 14).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395) in view of Sato et al (US 4,386,120).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The composition further contains a pharmaceutically acceptable diclofenac salt (page 4, line 1). However, Donati et al are silent with respect to the viscosity of (meth)acrylic acid-base polymer in aqueous solution. However, Sato et al teaches the formulation of easily water soluble sodium polyacrylate where in the viscosity of the solution is 50 - 700 c.p.s (column 5, lines 26-28). Therefore, it would have been obvious to one skilled in art at the time invention was made to use sodium polyacrylate in aqueous solution with viscosity of 50-700 c.p.s as taught by Sato into Donati's hydrogel mixture since a species of a genus will work properly, motivated by expectation of success.

7. Claims 12, 15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395) in view of Bernstein (EP 95512 A) and LaHann (US 4,313,958).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The hydrogel mixture preferably comprises a wetting agent chosen from polyhydric alcohols such as glycerol, propylene glycol, sorbitol etc in a concentration of 5 to

70 wt% (page 3, paragraph 0018 and 0019). However, Donati et al are silent with respect to the addition of pharmaceutically active ingredient "capsaicin". However, capsaicin is a well known pharmaceutically active ingredient as taught by Bernstein, where in the composition is used to treat psoriatic skin (abstract). Furthermore, LaHann teaches (abstract) the usefulness of "capsaicin" as a potent analgesic. Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add "capsaicin" to Donati et al's composition and thereby arrive at the claimed invention.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395) in view of Yamazaki et al (JP 06145049).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The hydrogel mixture preferably comprises a wetting agent chosen from polyhydric alcohols such as glycerol, propylene glycol, sorbitol etc in a concentration of 5 to 70 wt% (page 3, paragraph 0018 and 0019). However, Donati et al are silent with respect to the usage of magnesium hydroxide aluminum hydroxide co-precipitate as a cross-linking agent. However, aluminum magnesium hydroxide as a polyvalent metal salt is used as a cross-linking agent, to produce a cataplasma base having high tack and high base strength in a highly cross-linked

state free from transfer of plaster to skin during peeling cataplasma, as taught by Yamazaki (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add magnesium hydroxide aluminum hydroxide to Donati et al's composition to obtain the above mentioned advantages.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395).

Donati et al disclose a process for the preparation of hydrogel mixture consisting of thickening agent (sodium polyacrylate), wetting agent (polyhydric alcohols), cross-linking agent (Al compound) and water by mixing these and other optional ingredients in several stages. The process consists of adding polyhydric alcohol or wetting agent (sorbitol) to water. To this aqueous solution is added, in the form of aqueous solution, one half the quantity of cross-linking agent (dihydroxy aluminum glycinate), thickening agent (sodium polyacrylate). To this mixture thus obtained is added an aqueous mixture of optional ingredients such as polyvinyl pyrrolidine, (page 3, paragraph 0027; page 4, paragraph 0028-0030). Finally, an aqueous solution consisting of remaining parts of crosslinking agent, thickening agent and the active pharmaceutical agent are added. The water content of final composition is 29.73%, essentially the same as that described in the claims.

The prior art does not teach the same sequence of process steps as recited in the instant claim. The composition is taught by the prior art though the sequence of mixing components differs. However, it would have been obvious to one skilled in art at the time invention was made to alter the sequence and essentially arrive at the instant claim, absent evidence of unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karuna P. Reddy whose telephone number is (571) 272-6566. The examiner can normally be reached on Monday-Friday 8:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karuna P Reddy
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Art Unit 1713


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